HelioScreen

HelioNews

News about In Vitro Sun Protection Testing

HN 2013 N°15

Contents

Congress & Events

in-cosmetics Bangkok
2013 October 29-31th
Visit us on **Booth L31**

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Editorial

The In Vitro tests are the most accepted and used methods for photoprotection evaluation but the most important are the difficulties to make the results reliable between the numerous institutes which are now involved in this kind of testing. Although there are now rules and standards, it is far from being sufficient and anyway lots of institutes decide to keep their proper rules. Sometimes they even claim their solutions and methods are better than the International or European rules unless accepted with the ad hoc consensus. Customers don't know exactly what to check for reliable results or even trust the first company claiming they have a great experience - sometime in other kind of testing -.

*Our task is to demonstrate these In Vitro methods is far from being simple and requires know how and long experience. It is to contribute to put into the light **new uncontrolled** parameters and some proposal for improvement. We publish this year several papers, performed work and research with the major cosmetic and expert laboratories in France. I can state this is far from being finish! You will see in the next months some great improvement of In Vitro methods presented in Asia where Helioscreen open a new joint-venture with a laboratory in Bangkok.*

This has been our goal since I created the laboratory about 15 years ago (under our previous and former name Helioscience) and we never change our way. We are involved in research, we have the most updated equipment and are able to do very thing around the testing: Training, Control of sources, Control of substrate, etc. We have been audited by several cosmetic companies and followed a strict quality process now certified for years. As In Vitro UV testing are more and more recognized, there are plenty of new actors in this field but time comes for customers to know what to check in order to choose an institute as he does when buying raw materials. Our unchanging goal of quality and exigency will be the guaranty of the future of your satisfaction.

Dominique LUTZ, CEO Scientist Manager

I. Critical Wavelength assessment - «a false friend in reliability»

I.a. History

This is **BL Diffey** who introduced in **1994** a new criteria for a "**broad-spectrum**" classification of sun protective products. As a matter of fact the sun protection was then only evaluated with SPF (Sun Protection Factor) value. Some UVA methods existed with several standards but it was not yet considered the importance of the balanced repartition of the absorption spectrum.

The principle consisted in the evaluation of the cumulated absorption of UV light at each wavelength in order to compare the products with the expression of the specific wavelength where a certain level of cumulated absorption was reached. This wavelength is the so called **Critical Wavelength** (CW). The higher this specific wavelength is, the better the balanced repartition of the UV protection. BL Diffey demonstrated interest of this new index for determination of reliability of a sunscreen to protect against large range of solar spectrum.

The CW determination is only available by means of **In Vitro tests**. Indeed, the In Vitro method allows obtaining spectrum absorbance curve and only In Vitro method is able to express a ratio between the UVA and the UVB absorption with only one measurement.

«This method seems quite easy but most of the time, it is badly performed and results can be challenged.»

HelioScreen Asia

As a forerunner and one of the most worldwide expert in the evaluation In Vitro of the sun protection for cosmetics, HelioScreen jumps another important step in the worldwide promotion of these methods.

Thus, a joint and venture between the French HelioScreen Cie and the Thai Chemico Ltd Cie will be constitued to create the Asia representative of our French laboratory:

HelioScreen Asia Co., Ltd

Now, facilities with great knowledge and expertise on the In Vitro methods will be based in Bangkok **to serve all ASEAN and other Asian countries.**

You trust us for In Vitro UV testing in our French laboratory and you will also trust us in our Thai laboratory.

*Association of Southeast Asian Nations regroupe les pays suivants : Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Tahilande, Viet Nam.

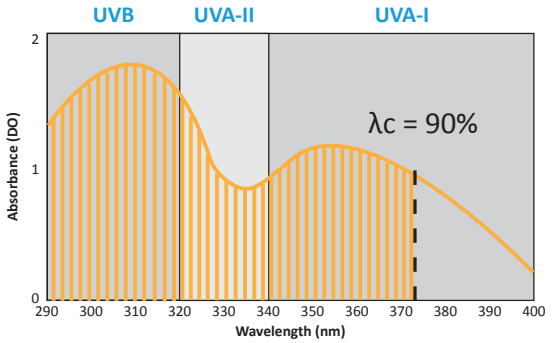


Figure 1. Critical Wavelength determination

The CW λc describes the range of protection over the entire UVR spectrum (290 - 400 nm). λc is the wavelength where the integral of the absorbance spectrum from 290 nm to λc equals 90% of the integral of the absorbance spectrum from 290 to 400 nm. The Figure 1 represents the CW determination and the equation here below explains the calcul method.

$$\int_{\lambda = 290\ nm}^{\lambda c} A(\lambda) \bullet d\lambda = 0.90 \bullet \int_{\lambda = 290\ nm}^{\lambda = 400\ nm} A(\lambda) \bullet d\lambda$$

where A(λ) is the monochromatic absorbance of sunscreen layer at wavelength λ; λc is the critical wavelength calculated to comply with the equation here above; and d(λ) is the wavelength step.

This method seems quite easy but most of the time, it is badly performed and results can be challenged. As a matter of fact,It is important to remind this characteristic of each product is mainly dependant of the **photostability of the product**. Clearly when there is an evolution of the level of absorption due to photodegradation, the CW can change dramatically.

«It is quite fundamental to check the test is leaded in the condition for the described method (Colipa or FDA)»

Nowadays, sunscreens **labelling** depends on the market zone but in all cases, there is a concern about the balanced protection UVB/UVA and most of the time the CW has to be be determined. This is the case in **USA and EU** with a CW over 370 nm considered by the **FDA** (Food Drug Administration) and the **Cosmetics Europe** (formerly Colipa) to provided UVB/UVA protection. Nevertheless, the conditions of measurement are not all the same due to an irradiation quantity totally different. As explained previously, it can impact on the CW value. It has been clearly demonstrated in a recent paper presented in the Florida **[1]**.

So this index which seems easy to measure may in fact lead to very different results depending on the conditions of irradiation imposed by the standard (USA or EU) and also the photo stability of the product! In EU the quantity of irradiation is variable and depends on the value of UVA-PF before irradiation and in USA it is a fixed quantity of 4 MEDs (Minimal Erythema Dose). Unless there are clear description of the condition of measurements for each standard and the possibility to have a decreasing value of CW for product not totally photostable, lots of CW determination are proposed without irradiation in some laboratories!

«It is very important to follow the standards for labeling. This sounds evident but unfortunately you can check in some institutes it is not always the case.»

I.b. How well determinate the critical wavelength?

First of all it is quite **fundamental to check** the test is leaded in the condition for the described method (Colipa or FDA) and the ad hoc dose of irradiation with a possibility to control it as described for other In Vitro method requiring an irradiation (for example ISO 24443:2012)

But there are also other requirements and, we present you a table (see Table 1) with a non- exhaustive check-list of the elements. It guarantees the relevance of Critical Wavelength results according to the two standards. It is very important for you to check if the laboratories follow correctly the standards in order to be safe if your products are controlled by authorities.

I.c. Conclusion

As said previously, in order to have **reproducible results**, it is very important to follow the standards for labelling. This sounds evident but unfortunatly you can check in some institutes it is not always the case. The table here below shows principal differences according to different standard for CW assessement. When following the rules, it is still dependant of plenty of other conditions which must be mastered. HelioScreen has done a huge work in order to improve In Vitro tests. For example, we demonstrate importance of temperature at substrate surface for reproductible CW results. Clearly, other parameters could also influence CW value. CW determination is not so simple it seems...

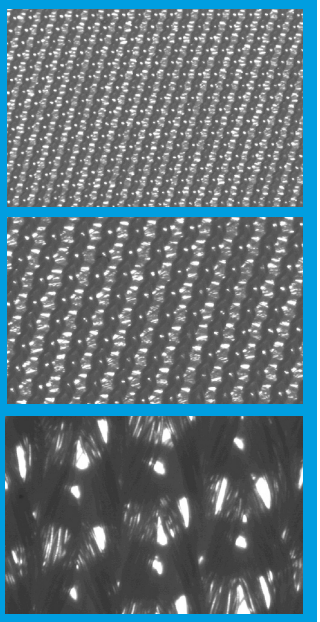
Table 1. Requirements of standards for Critical Wavelength determination

Concern	Description	FDA	Cosmetics Europe
Substrate	**Topographic parameters strictly described** and must be respected.	1. PMMA material - Sa = 2-7 µm *Note: Substrate roughness variation can conduce to CW results different. It's preferred a plate with 5µm roughness. [1]* 2. At least 3 plates and at least 5 measurements per plate.	1. PMMA material Ra = 4.853 ± 0.318 µm Rv = 13.042 ± 0.628 µm Rdq = 11.122 ± 1.289 ° A1 = 239.750 ± 44.510 µm²/mm SSc = 0.033 ± 0.013 L/µm Vw = 1.044E-6 ± 6.192E-7 mL/m² 2. At least 3 plates
UV spectrometer	Regular intervals, c**alibration by test requirement** with reference materials: 1. Wavelength accuracy 2. Dynamic range	1. - 2. «sufficient to measure transmittance accurately trhough a highly absorbing sunscreen product at all UV wavelength (between 290 and 400 nm)»	1. Peak at 361 ± 1 nm 2. Minimum limit 2.2 AU
Solar Simulator	The **spectral** and **level irradiance** of the artificial **UV source** are very importants for reproducible results.	1. Regular calibration at least once a year 2. Total irradiance limit of 1500 W/m² for all wavelength of 250 - 1400 nm 3. 20% beam uniformity requirement 4. UVA II (320-400 nm) ≥ 20% total UV (290-400 nm) and UVA I (340-400 nm) ≥ 60% total UV. 5. Irradiation dose equals to 4 MED - Fixed at 800 J/m²-eff	1. Regular calibration at least once a year 2. Total UV irradiance between 50 - 140 W/m² for wavelength 290 to 400 nm 3. Irradiance ratio of UVA to UVB between 8 - 22 4. Temperature below 40°C 5. Irradiation dose depends on the UVA PF value before irradiation
Spreading method	The **quantity** and **spreading method** are very important to assure reproducibility.	1. 0.75 mg/cm² 2. With fingercot 3. Two-phase spreading action less than 30 sec each 4. At least 15 min	1. 1.3 mg/cm² 2. Without fingercot 3. Two-phase spreading action less than 30 sec each 4. At least 15 min

[1] D. Lutz, J. Ongenaed and C. Guy. FDA Rule for Broad-spectrum Labeling: Key Substrate Findings. C&T Vol. 126, No. 10, 732-742 (October 2011)

New services for textile materials implemented by our laboratory

The HelioScreen laboratory is one of the most important actor of In Vitro sunscreen testing. As an expert in the UV field, it seems logical to propose also tests in textile field. We developed our know-how in textile tests in order to be in accordance with different international standards.



HelioScreen offers complete range of evaluation of the accurate label products as «UV Protective» following the different published standards according to market zone. Since long time, you trust us for evaluation of your sunscreens and you can be now also trus us for evaluation of your textile.

Standards for textile materials UV In Vitro evaluation

European

- **EN 13758-1**: Sun Protective Clothing, Method of test for appareil fabrics

- **EN 13758-2**: Solar UV properties - Classification and marking of appareil

USA

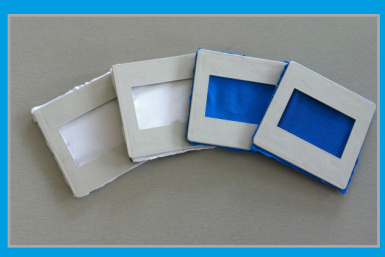
- **AATCC Test Method 183-2010**: Transmittance or Blocking of Erythemally Weighted Ultraviolet Radiation through Fabrics.
  This is the standard used to determine the protection rating for a fabric or textile.

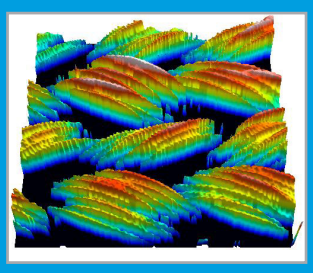
- **ASTM D6544-12**: Standard Practice for Preparation of Textiles Prior to Ultraviolet (UV) Transmission Testing.
  This is the standard used to determine a product's sun protectiveness at the end of its life cycle.

- **ASTM D6603-12**: Standard Specification for Labelling of UV-Protective Textiles
  This is the standards used to describe how a garment or fabric is laveled based on the above tests results.

AUSTRALIA-NEW ZEALAND

- **AS/NZS 4399:1996**: Sun protective clothing - Evaluation and classification





II. Influence of Temperature on Substrate Surface on In Vitro SPF

II.a. Introduction

In previous HelioNews (HN14), we presented you the **influence of surface energy** of substrate on In Vitro SPF. But clearly, in order to have a futur harmonized In Vitro SPF method, both **correlation** and **reproducibility** are required.

Although several keys parameters have been identified since first In Vitro method for improvement of reproducibility, we studied a **new** parameter that has not been yet considered: the **substrate surface temperature** during application, spreading and drying steps. This work is part of a larger reproducibility optimization program that aims to identify, demonstrate and control all variables that can influence In Vitro SPF.

This article is partly extracted from publication "UV Transmission Assessment: Influence of Temperature on Substrate Surface" by S. MIKSA, D. LUTZ and C. GUY. Cosmetics & Toiletries (July 2013).

II.b. Material & Methods

Temperature control:
In this study, we studied graduated temperature levels, from 20°C to 35°C by steps of 5°C. The temperature was controlled by means of the **HD-THERMASTER** developped by our laboratory. The temperature was maintained at substrate surface by means of a metallic support when the plate was taken off the appliance.

Substrate:
In order to assure the higher reproducibility of other parameters, the **HD6 substrate** was used. The topographic parameters are controlled and guaranteed for HD6 within the Colipa and ISO 24443 requirements.

Product:
Thirty-seven sunscreen products covering various formulations are chosen.

Transmittance measurements:
The **Labsphere UV-2000S** is used to measure the UV transmittance through the thin product layer.

Procedure:
We applied product in order to have a rate of **1.3 mg/cm²**. Immediately after, the product was spreaded on whole surface by a specific protocol which guaranteed a high repeatability. After the drying step, each plate was measured (2 plates per product). During the whole process -application, spreading and drying- the temperature was controlled.

II.c. Results

By means of the new **HD-THERMASTER** device, a great impact of temperature of substrate surface is demonstrated. Indeed, more than **80% of tested products** show a **SPF variation** only with a difference of 5°C. The following figure 2 show mean of all SPF values according to temperature.

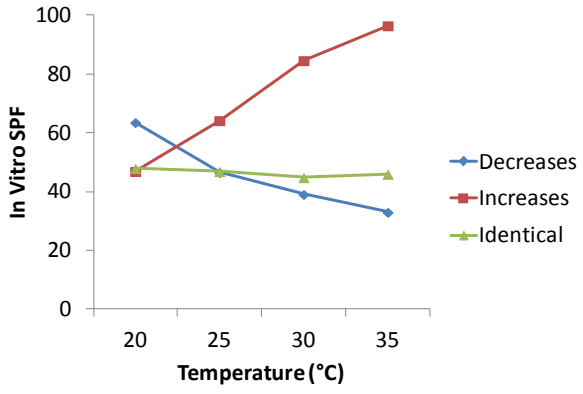


Figure 2. Influence of temperature variation on In Vitro SPF for all products

Three behaviours can be discerned, a **SPF increases with temperature increases**, a SPF decreases with temperature inscreases and no thermo-sensitive products.

We also studied a **variation of 2°C** on two thermo-sensitive products (see figure 3). The results show clearly an **impact of temperature on substrate surface on SPF value** even with a slighly variation of 2°C.

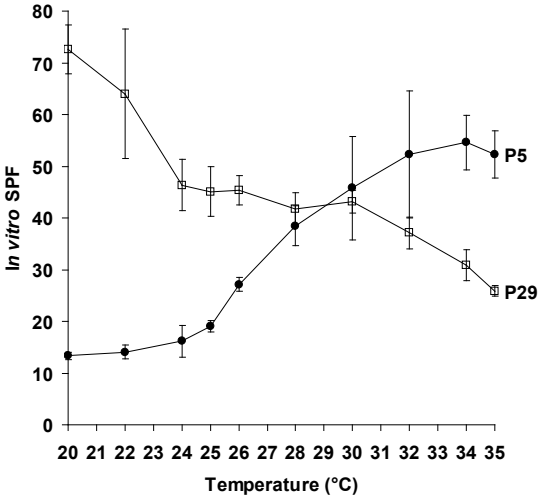


Figure 3. In Vitro SPF variation according to slightly temperature variation

II.d. Conclusion

The following figures show mean of all SPF values according to temperature. The figure 2 for a SPF increases with temperature increases, for a SPF decreases with temperature inscreases and for no thermo-sensitve products. Furthermore, as said previously, only 2°C variation can influence In Vitro SPF values (see figure 3).

From this study, it appears that the **majority of product is sensitive to temperature on substrate surface modification**. By mastering this parameter, we improve the **repeatability of In Vitro sunscreen evaluation**.

Clearly, in order to propose a futur harmonized method for In Vitro SPF assessment, the temperature on substrate surface should bet be controlled. The next steps in this process will be to identify, demonstrate and control the other variables that can influence In Vitro SPF.

Highlight of the In Vivo/In Vitro packs

Development of a sunscreen product is performed by In Vitro method for ethical, practical and economical reasons. But in order to be in accordance with regulatory, In Vivo and In Vitro tests are compulsory.

As **a partner** for your sunscreen product evaluation, we propose different packs allowing **In Vivo SPF** determination* (ISO 24444:2010 and FDA method), **In Vitro UVA-PF** (ISO 24443:2012 and Colipa rev. 2011) and **In Vitro Critical Wavelength** (Colipa rev. 2011 and FDA method).

These packs are more and more requested by our customers for product labelling. HelioScreen is pleased to propose you also these packs if you need to label a sunscreen product. Contact us if you need more informations.

*Tests implemented by external partnership laboratories

New documents for HelioScreen's presentation

CATALOG
Global presentation of HelioScreen. Discover general aspects with also all tests and services proposed by HelioScreen.

QUALITY MANUAL
BVQI ISO 9001:2008 certified, HelioScreen presents you its quality system.

ACTIVITY REPORT
As an international company, HelioScreen presents you its key figures in this paper.

Last scientific articles

Cosmetics & Toiletries, July2013:
- S. Miksa, D. Lutz and C. Guy. *UV Transmission Assessment: Influence of Temperature on Substrate Surface.*

International Journal of Cosmetic Science, July 2013:
- M. Pissavini, O. Doucet, B. Diffey. *A novel proposal for labelling sunscreens based on compliance and performance.*

International Journal of Cosmetic Science, June 2013:
- E. Dupont, J. Gomez, D. Bilodeau. *Beyond UV radiation: A skin under challenge.*
- E. Gilbert, F. Pirot, V. Bertholle et al. *Commonly used UV filter toxicity on biological functions: review of last decade studies.*

Cosmetics & Toiletries, May2013:
- D. Lott. *Sun Care Use: Beach Survey*
- S. Wiechers, P. Biehl et al. *Titanium Dioxyde Particle Size vs. Sun Protection Performance.*

Last patents

- WO 2013039483 A1
Y. Kawasaki, K.Shimizu, N. Yamamoto, M. G. Lepage. US Cosmetics Corporation. *SPF enhanced extended color bulk powders and methods of making thereof.*

- US 20130171080 A1
A. Sarkar, A. Saxena, S. Tiwari, B. Falk. Momentive Performance Materials Inc. *Personal care compositions containing end-functionalized ionic silicone.*

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